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EXAMINER

MARSCHEL, A

ART UNIT

PAPER NUMBER

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18M2/0402

1807

DATE MAILED:

04/02/96

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

5-30-95
8-14-95
10-16-95
12-29-95

This application has been examined Responsive to communication filed on 3 month(s), 49 days from the date of this letter. This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), 49 days from the date of this letter. Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. Notice of References Cited by Examiner, PTO-892.
3. Notice of Art Cited by Applicant, PTO-1449. (12 sheets)
5. Information on How to Effect Drawing Changes. (Rev. 1 PTO-948)
2. Notice of Draftsman's Patent Drawing Review, PTO-948.
4. Notice of Informal Patent Application, PTO-152.
6.

Part II SUMMARY OF ACTION

1-30

are pending in the application.

1. Claims _____ are withdrawn from consideration.

Of the above, claims _____ have been cancelled.

2. Claims _____ are allowed.

3. Claims _____ are rejected.

4. Claims _____ are objected to.

5. Claims _____ are subject to restriction or election requirement.

6. Claims _____ are subject to restriction or election requirement.

7. This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. Formal drawings are required in response to this Office action.

9. The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are acceptable; not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).

10. The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been approved by the examiner; disapproved by the examiner (see explanation).

11. The proposed drawing correction, filed _____, has been approved; disapproved (see explanation).

12. Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has been received not been received been filed in parent application, serial no. _____; filed on _____.

13. Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. Other

EXAMINER'S ACTION

AM

PTO-326 (Rev. 2/93)

08/454,529

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The present title is only directed to probes whereas, in contrast, methods of probe preparation are presently claimed.

The following is a quotation of the first paragraph of 35

U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-30 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited to methods wherein the probe selection is defined as to be determined by both positive and negative control organisms. In order to select probe sequences that are useful as cited in claims 1-30 someone of ordinary skill in the art would have to test potential nucleic acid probes by selecting positive and negative control organisms (It is noted that "non-viral organism or group of non-viral organisms", cited in line 5 of claim 1, is unclear as to whether this means a single organism or all organisms whether known or unknown by mankind.), selecting hybridization conditions to use during the assay, selecting segments from the ribosomal sequences within the selected control organisms which are well known to be variable sequences since conserved sequences by their very nature would not be usable as

desired as set forth in claim 1 etc. and then perform test assays on each potential probe, potential assay condition, etc. until the probe with the desired properties was found. This is the entirety of the process required to select hybridization probes. This total experimentation requirement invites experimentation for enablement rather than supplies disclosure which eliminates undue experimentation. Such an invitation to experiment falls far short of enabling disclosure and is the basis for this rejection. See M.P.E.P. §§ 706.03(n) and 706.03(z).

Claims 1-30 are rejected, as discussed below, under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-30 at certain citations contain the phrases "sufficiently complementary to" without clearly defining the metes and bounds of the complementary practice. For example, does this mean 100% complementary or may be inclusive of some lesser percentage as is commonly given in the art? Clarification is requested as to what is meant by the complementarity wording in the claims.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary

skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

Claims 1-30 are rejected under 35 U.S.C. § 103 as being unpatentable over Kohne (P/N 4,851,330).

The invention is directed to hybridization probes and hybrids formed therefrom that are generically specific to a particular microorganism via being directed to variable regions of ribosomal sequences via selection of such regions via screening.

Kohne discloses the preparation by screening and use of ribosomal sequences to variable regions for hybridization probe practice via formation of hybrids in hybridization assays. Since the instant application is presently broadly claiming probes that are selective to a microorganism via ribosomal sequences, this is clearly suggests and given a reasonable expectation of success given the generic disclosure of Kohne for such practice.

Thus, it would have been obvious to someone of ordinary

skill in the art at the time of the instant invention to practice the preparation of ribosomal hybridization probes that are specific to a particular microorganism species since this is what the entire disclosure of Kohne is directed to.

Enclosed is an executed PTO Form 1449 with some citations thereon lined through due to a lack of a date of publication.

The disclosure is objected to because of the following informalities:

On page 117, a blank is present that lacks filling in.

Appropriate correction is required.

No claim is allowed.

Papers related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Group 1800 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 305-3014 or (703) 308-4227.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703) 308-3894.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

March 29, 1996

Ardin H. Marschel
ARDIN H. MARSCHEL
PATENT EXAMINER
GROUP 1800